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| PRE-APPEAL BRIEF REQUEST FOR REVIEW | | Docket Number (Optional) | | | |
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| | | 8627-51 (PA-5322-RFB) | | | |
| I hereby certify that this correspondence is being deposited with the | Application N | umber | Filed | | |
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| Patents, P.O. Box 1450, Alexandria, VA 22313-1450" [37 CFR 1.8(a)] | | | <u> </u> | | |
| November 3, 2006 | First Named Inventor | | | | |
| Signature R | Brian Bates | | | | |
| Signature / | Art Unit Examiner | | | | |
| Typed or printed Richard E. Stanley, Jr. | | 7.2.4 | rah K. Webb | | |
| Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request. This request is being filed with a notice of appeal. The review is requested for the reason(s) stated on the attached sheet(s). Note: No more than five (5) pages may be provided. | | | | | |
| I am the | | | | | |
| applicant/inventor. | K | Sign | nature | | |
| assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96) | R: | ichard E. Sta | 1 | | |
| attorney or agent of record. Registration number | 3: | 12-321-4279 | | | |
| | · — | Telepho | ne number | | |
| x attorney or agent acting under 37 CFR 1.34. | | November 3, | , 2006 | | |
| Registration number if acting under 37 CFR 1.34 45,662 | - Date | | | | |
| NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*. | | | | | |
| *Total of forms are submitted | | | į. | | |

This collection of information is required by 35 U.S.C. 132. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11, 1.14 and 41.6. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

NOV 0 7 2006 by certify that this correspondence is being transmitted via facsimile he U.S. Patent and Trademark Office at number 571-273-8300 and is being deposited with the U.S. Postal Service as First Class Mail with sufficient postage in an envelope addressed to: Mail Stop AF Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450 on November 3, 2006 **Date of Deposit** Richard E. Stanley, Jr., Reg. No. 45,662 Name of Applicant, Assignee or Registered Representative Signature November 3, 2006

Date of Deposit

Our Case No. 8627-51 Client Ref. No. PA-5322-RFB

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

| In re Applica | ation of: |) | · | |
|---------------|------------------------------------|-------------|--------------------------|--|
| | Brian Bates |) | | |
| Serial No. | 10/092,095 |)) | Examiner: Sarah K. Webb | |
| Filing Date: | March 6, 2002 |)) | Group Art Unit No.: 3731 | |
| | FIALLY COVERED ALUMINAL SUPPORT CF |))) | | |

PRE-APPEAL BRIEF REQUEST FOR REVIEW

Mail Stop AF Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Dear Sir:

In response to the Office Action dated August 9, 2006, Applicant requests review of the final rejection in the above-identified application. As explained in more detail below, this review is being requested because of clear errors in the Examiner's rejections, and the Examiner's omission of essential elements needed for a prima facie rejection. A Notice of Appeal accompanies this Request.

REMARKS

Claims 40-50 and 73-74 are pending in the application. The most recent listing of the claims is included with Applicant's RCE filed on December 13, 2005. Claim 40 is the only independent claim. The Examiner has rejected the claims under 35 U.S.C. § 103(a) based on Summers, McCrory, Myers et al. and Wulfman et al.

Applicant contends that the Examiner has used impermissible hindsight to piece Applicant's claimed invention together like a jigsaw puzzle. The Examiner has not articulated a proper motivation to combine the cited prior art in the proposed manner. As such, the Examiner has not established a prima facie case of obviousness.

The Law of Obviousness

35 U.S.C. § 103 requires that the subject matter of the claimed invention be considered "as a whole." The ultimate question under 35 U.S.C. § 103 is "whether the claimed invention as a whole would have been obvious," "not whether the differences [between the claimed invention and the prior art] themselves would have been obvious." Stratoflex, 713 F.2d at 1537 (Fed. Cir. 1983); Schenk, 713 F.2d at 785 (Fed. Cir. 1983).

"To prevent the use of hindsight based on the invention to defeat patentability of the invention, this court requires the examiner to show a motivation to combine the references that create the case of obviousness. In other words, the examiner must show reasons that the skilled artisan, confronted with the same problems as the inventor and with no knowledge of the claimed invention, would select the elements from the cited prior art references for combination in the manner claimed." *In re Rouffet*, 149 F.3d at 1357 (Fed. Cir. 1998).

"That all elements of an invention may have been old (the normal situation), or some old and some new, or all new, is however, simply irrelevant. Virtually all inventions are combinations of old elements. A court must consider what the prior art as a whole would have suggested to one skilled in the art." *Environmental*, 713 F.2d at 698 (Fed. Cir. 1983).

"The 'as a whole' instruction in title 35 prevents evaluation of the invention part by part. Without this important requirement, an obviousness assessment might break an invention into its component parts (A + B + C), then find a prior art reference containing A, another containing B, and another containing C, and on that basis alone

declare the invention obvious. This form of hindsight reasoning, using the invention as a roadmap to find its prior art components, would discount the value of combining various existing features or principles in a new way to achieve a new result—often the very definition of invention." *Ruiz*, 357 F.3d at 1275 (Fed. Cir. 2004).

"This line of reasoning would import hindsight into the obviousness determination by using the invention as a roadmap to find its prior art components. Further, this improper method would discount the value of combining various existing features or principles in a new way to achieve a new result—often the essence of invention." *Princeton*, 411 F.3d at 1337 (Fed. Cir. 2005).

Argument

Contrary to the admonitions of the Federal Circuit, Applicant contends that the Examiner has engaged in impermissible hindsight to reconstruct Applicant's invention piece-by-piece from the prior art using Applicant's claims as a roadmap. Like the example given in *Ruiz v. A.B. Chance*, the Examiner has broken Applicant's claims into component parts A, B and C to declare the claims obvious. In the Examiner's analysis, component A is the structure of the stent (Summers). Component B according to the Examiner is the graft layer (McCrory). Component C according to the Examiner is the manner of attaching the graft layer to the stent (Myers et al.). Using hindsight and the Applicant's claims as a roadmap, the Examiner has combined components A, B and C of Summers, McCrory and Myers et al. to reconstruct Applicant's claims.

However, the motivation to combine Summers, McCrory and Myers et al. in the manner that the Examiner has attempted is lacking. The Examiner argues that Summers discloses attaching a graft material to the stent structure. However, the Examiner admits that Summers does not disclose a graft material extending only a partial distance along the circumference. In fact, the Examiner relies upon two summary paragraphs at the end of Summers that broadly describe alternative embodiments. (Col. 11, lines 25-52). None of the drawings in Summers actually shows a graft attached to the stent. Moreover, there is no description of how a graft layer extending only a partial distance along the circumference would be attached to the stent structure of Summers.

The Examiner argues that McCrory satisfies part of the omission in Summers because McCrory discloses a stent frame with a permeable portion and a less permeable portion. (Col. 3, lines 1-22). However, in the only embodiment in McCrory where the occlusion device is used to treat an aneurysm that is adjacent perforating vessels, McCrory teaches away from the use of a stent with a graft extending only a partial distance along the circumference. This is one of the advantages of Applicant's claimed stent as shown in Figure 10 of Applicant's specification. By contrast, McCrory states that when perforating vessels are adjacent the aneurysm, it is difficult to orient the partial graft layer relative to the aneurysm. (Col. 4, line 58 to col. 5, line 10). In this situation, McCrory recommends that the stent structure be made less permeable after the occlusion device is deployed. Moreover, as shown in Figure 3D of McCrory, the less permeable portion extends around the entire circumference of the stent when adjacent perforating vessels exist.

The Examiner admits that Summers and McCrory do not disclose Applicant's claimed structure for attaching the partial graft to the stent structure. The Examiner relies upon Myers et al. for this missing piece of the puzzle. However, Myers et al. does not even refer to a graft layer that extends only a partial distance along the circumference of the stent. In all of the embodiments disclosed in Myers et al., the graft layer extends around the entire circumference of the stent. Myers et al. makes no suggestion that the graft layer could extend only partially along the circumference.

Examiner's Response

The Examiner relies upon conclusions that it would have been obvious to combine Summers, McCory and Myers et al. The Examiner's position is summarized on page 4 of the August 9 Office action at paragraph 3, where the Examiner states: "All of the claimed elements are shown in the prior art and there is proper motivation for combining the elements." However, this is not a proper showing of suggestion or motivation to combine different prior art references together. It is not enough to merely show that all of the pieces of the puzzle existed in the prior art.

In particular, the Examiner's comments about McCrory are unintelligible. The examiner states that "[Figure 3A] is relied upon for the rejection, because it involves in vivo formation of a graft portion. The embodiment relied upon for the rejection is the

embodiment of Figure 2A." (8/9/2005 Office Action at 4-5 \P 4). The Examiner appears to agree with Applicant that Figure 3A is irrelevant to the claimed invention since the graft layer is placed on the stent after the stent is implanted. If the Examiner agrees on this point, then the Examiner should not be relying upon Figure 3A of McCrory.

Likewise, the Examiner's basis for combining McCrory with Summers is lacking. Contrary to the Examiner's argument, Summers is not primarily directed to stent-grafts. Summers only discloses that the stent may also be used as a stent-graft. There is no suggestion that the structure in Summers may be useful as a partially coated stent.

Further, the Examiner's response does not even refer to Myers et al. or provide a suggestion or motivation to combine Myers et al. with Summers and McCrory. The only comment that the Examiner makes about the combination of Myers et al. with Summers and McCrory is on page 3 in paragraph 1 of the 8/9/2006 Office Action. Specifically, the Examiner states: "Since McCrory teaches that any known attachment mechanism can be used, it would have been obvious to one of ordinary skill in the art at the time the invention was made to attach the graft of the modified Summers device by either of the attachment means taught by Myers." However, this is a mere conclusion without any factual support. In fact, the attachment mechanism disclosed in Myers et al. would not work on McCrory because McCrory discloses a mesh stent. The structure of Myers et al. and McCrory are completely different. Furthermore, Myers et al. does not disclose that the attachment mechanism could be used for a partially coated stent.

For the foregoing reasons, it is clear that Final Office Action fails to set forth a prima facie case of obviousness. Accordingly, Applicant respectfully requests that the rejections in the present application be withdrawn.

Respectfully submitted,

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Attorney for Applicant

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